

examiner, claims 29-144, 123-126, 129-131 and 134-137 having been withdrawn by the examiner.

**35 U.S.C. § 102 rejection of claims 1-21**

The examiner has rejected claims 1-21 under § 102 as being anticipated by Webster, et al., U.S. Pat. No. 6,123,699. The examiner states that Webster discloses a deflectable catheter assembly comprising: a catheter shaft (interior of element 91); a tendon (31) disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section (as in figure 8 for example) and said first lumen located off-center of said catheter shaft at said catheter distal section (as in figure 6A and 6B, said tendon being able to deflect said catheter distal section when being pulled on (as in figures 1 and 7); and a catheter handle (14) coupled to said catheter shaft, said catheter handle including a first control mechanism (63 for example) to control said tendon, and slip bands (33). The examiner goes on to assert that Webster also comprises a needle "(not shown but inherent, see paragraphs beginning at column 3, line 16)" or a plurality of needles, disposed within said lumen of said catheter shaft also "(not shown but in fifth lumen and an inherent feature of Webster, also concerning claims 10-11)."

The examiner then states that with regard to claims 5 and 6, Webster further comprises an axial spine (91 or 92) disposed around and over a first section of said tendon, said first section being substantially aligned with said catheter proximal section, said axial spine to resist axial compression along said catheter proximal section (see figure 11), and a flexible tendon sheath (95) coupling to said axial spine, said flexible tendon sheath extending a second section of said tendon and said second section being substantially aligned with said catheter distal section (see figures 1-14).

Finally, with regard to claim 8 and 9, the examiner states that Webster discloses: a tip electrode (29) located at the tip of said catheter distal section and coupled to a conductive lead that extends out of said catheter shaft and at least one additional electrode (28); a deflectable catheter fully capable of all flexibility requirements in claims 16-17 (see figure 7); and a pre-shaped guide sheath (92, 91) disposed around said catheter shaft that is fully capable of satisfying all functional, structural, and operational limits of the claims as written.

Applicants traverse.

**Applicants' response**

Claim 1 of the present application explicitly requires:

a tendon disposed within a first lumen of said catheter shaft,  
**said first lumen being approximately centrally located  
within said catheter shaft** at said proximal section of said  
lumen and said first lumen located off-center of said catheter  
shaft at said catheter distal section ... (emphasis added)

To the contrary, Webster discloses that:

A puller wire [which the examiner describes as a "tendon" to  
relate it to the current application] 31 **extends from the  
control handle 14 through each of the outer lumens 17  
in the catheter body 12** and into aligned outer lumen 23 of  
the tip section 13. (emphasis added)

The current catheter and the Webster catheter are clearly different. In the current catheter assembly the tendon is deployed down an approximately central catheter lumen to the catheter tip where it is then redirected to an off-center configuration. In Webster, the puller wire 31 is always deployed in an off-center lumen. Not only is this construct unambiguous from the plain language of Webster as provided above, it is very clear in the numerous figures in Webster, for example, figures 2, 3, 6B, 11 and 13, wherein catheter shaft 12 is labeled as are puller wires 31 and off-center lumens 17.

Since claims 2-21 depend from claim 1, they must all include all of the limitations of claim 1 including the initially centrally-located tendon, a feature that is absent in Webster.

Based on the above, it is evident that Webster does not anticipate any of claims 1-21 of the current invention. The examiner is requested to reconsider and withdraw the rejection.

**35 U.S.C. § 103 rejection of claims 22-28**

The examiner has rejected claims 22-28 under § 103 as being unpatentable over Webster in view of Edwards, et al., U.S. Pat. No. 6,254,598. The examiner admits that Webster is silent as to the medical device comprising a needle or a plurality of needles with at least one inflatable balloon coupling to said plurality of needles (and with a divergent angle), tube mechanism with needle stop disposed within a lumen of a catheter shaft being extendable from and retractable into the catheter distal section and

a control in the catheter handle. In the examiner's view, however, Edwards discloses these elements and the examiner is further of the opinion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Webster catheter with the needles/balloon mechanism of Edwards since "such a modification would provide the catheter with the needles/balloon mechanism for providing a unique and direct medical treatment operation."

Applicants traverse.

#### **Applicant's response**

Since, for the reasons discussed above, Webster has no bearing whatever on the current invention and since Edwards as explicated by the examiner adds nothing to Webster to overcome Webster's non-applicability, the combination of Webster and Edwards cannot and does not render the current invention obvious. The examiner is requested to withdraw the rejection.

#### **35 U.S.C. § 103 rejection of claims 115-122, 127, 128, 132 and 133**

The examiner has rejected claims 115-122, 127, 128, 132 and 133 under § 103(a) as being unpatentable over Webster in view of Edwards and further in view of Balbierz, U.S. Pat. No. 6,770,070. In the examiner's view, Webster in view of Edwards discloses the claimed invention except for using and coupling pressure sensors to a needle. The examiner, however, is of the opinion that Balbierz provides this teaching and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the Webster catheter as modified by Edwards to use the Balbierz needle-coupled pressure sensors since such a modification would provide the catheter with using and coupling pressure sensors to a needle for providing specific diagnostic feedback mechanism to the catheter.

The examiner admits that, with regard to claims 132 and 133, Webster/Edwards is silent as to the needle being made of a polymer. The examiner argues, however, that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the needle of a polymer material, since it has been well within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Applicants traverse.

#### **Applicants' response**

Since, for the reasons discussed above, Webster has no bearing whatever on the current invention and since neither Edwards nor Balbierz nor the combination of the two adds anything to Webster to overcome Webster's non-applicability, the combination of Webster, Edwards and Balbierz cannot and does not render the current invention obvious.

With regard to the examiner's statement that it would have been obvious to one skilled in the art to simply make a needle of a polymer, applicants in particular traverse. The examiner is requested to provide objective evidence corroborating this entirely unsupported and, in applicants' view, erroneous assertion.

Applicants request that the examiner reconsider and withdraw the rejection.

### CONCLUSION

Applicant does not believe any fee is due with this response. If this is incorrect, the Commissioner is authorized to charge any fee(s) due to Squire Sanders and Dempsey, L.L.P. Deposit Account No. 07-1850.

If the examiner would like to discuss this response or any other aspect of the present application, he is invited to telephone the undersigned at (415) 954-0200.

Date: January 11, 2007

Respectfully submitted,

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